

94. (New) A method for altering the association of immune complexes and B cell follicles in a patient comprising administering an amount of an antibody directed against surface LT ligand.

### Remarks

#### Informalities

Applicants are in the process of obtaining signatures for the new declaration and will submit the newly executed declaration in a separate communication.

#### Amendments

##### *In the specification:*

As requested by the Examiner Applicants have amended the specification to reflect the current address of the ATCC and have disclosed the full name and address of the ATCC upon its first appearance in the specification.

Applicants have also added a paragraph on the Related Applications to the above referenced application.

##### *In the claims:*

Claims 1-16 and 19-35 are pending in this application. Claims 1-16 and 19-35 have been canceled without prejudice or disclaimer of the previously claimed subject matter and solely to promote prosecution of the claims; Applicants reserve the right to prosecute the subject matter of these claims in one or more divisional or continuation applications. Claims 51-94 have been added. The pending amended claims are provided in Appendix A below in accordance with section 1.121. Claims 51, 52, 56-74, 78-85, 89-94 are equivalent in subject matter to pending claims 2-16, 20-27, 30-35 and include limitations of canceled claims 1, 19, and 29, respectively. Claims 53, 75 and 86 are directed at the ligand binding domain and are supported for example in the specification at page 11, lines 11-12 and page 14, lines 20-22. Claims 54-55, 76-77 and 87-88 are directed at heterologous fusion proteins and are supported for example in the specification at page 29, lines 20-33. The amendments to the claims are supported by the specification and no new matter has been introduced. Entry of these amendments is respectfully requested.

#### Rejection Under 35 U.S.C. § 112 First Paragraph

Claims 1, 3, 4, 9, 13, 15, 16, 19, 21, 22, 26, 28, 29, 34 and 35 are rejected under 35 U.S.C. § 112, first paragraph on various grounds. Applicants respectfully traverse these rejections.

*Claims 1, 3, 4, 15, 16, 19, 21, 22, 28, 29 and 35*

*Written Description*

Applicants note with appreciation the Examiner's statement that the specification provides descriptive support for three subgenus species in the LT- $\beta$ -R blocking agent genus, namely, soluble LT- $\beta$ -R, anti- LT- $\beta$ -R antibody and anti-LT ligand antibody. The Examiner asserts however that the specification does not provide descriptive support for the recitation of the genus "LT- $\beta$ -R blocking agent." Applicants respectfully traverse this rejection.

"A specification may, within the meaning of 35 U.S.C. section 112, paragraph 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses." Utter v. Hiraga, 845 F.2d 993 (Fed. Cir. 1988). Applicants submit that LT- $\beta$ -R blocking agent is specifically described throughout the instant specification (see for example, page 14, lines 1-10, in which Applicants describe the common functional elements of a LT- $\beta$ -R blocking agent for use in the present invention). Furthermore, on page 14, lines 5-10 and page 20, lines 22 – page 21, line 7, exemplary species are described including soluble LT- $\beta$ -R; anti-LT- $\beta$ -R antibody; anti-LT ligand antibody, including anti-LT- $\alpha$ , anti-LT- $\beta$ , anti-LT $\alpha/\beta$  antibodies and small molecule inhibitors of LT- $\beta$ -R.

As such Applicants submit that the instant specification does provide descriptive support for the recitation of the genus LT- $\beta$ -R blocking agent and therefore satisfies the requirement under 35 U.S.C. section 112, paragraph 1.

*Enablement*

Applicants note with appreciation the Examiner's statement that the specification is enabling for at least three subgenus species of LT- $\beta$ -R blocking agents, including soluble LT- $\beta$ -R, anti- LT- $\beta$ -R antibody and anti-LT ligand antibody. The Examiner alleges however that the term "blocking agent" broadly reads upon any substance which would interfere with LT- $\beta$ -R /lymphotoxin interaction and that Applicants have not provided examples for all such compounds (emphasis added). Applicants submit that such a requirement by the Examiner is not required under 35 U.S.C. section 112, paragraph 1 and is against established case law. It is a well established principle that patent Applicants are not required to disclose every species encompassed by their claims. See In re Vaeck, 947 F.2d. 488 (Fed. Cir. 1991). Applicants submit that the instant specification provides ample examples and guidance to support the pending claims.

Nonetheless, solely for the purpose of advancing prosecution Applicants have canceled claims 1, 3, 4, 15, 16, 19, 21, 22, 28, 29 and 35. The cancellation of these claims is not to be construed as an agreement by the Applicants of the Examiner's position; in fact, Applicants for the reasons stated above, submit that the Examiner is incorrect in rejecting these claims under 35 U.S.C. section 112, paragraph 1. Moreover, Applicants specifically reserve the right to prosecute the cancelled subject matter at a later date through a divisional or continuation application.

*Claims 9, 13, 26 and 34*

*Biological Deposits*

It is alleged that the claims are not sufficiently enabled by the specification absent a deposit of the hybridoma cell line that produces BDA8 and B9. Applicants submit that the cell lines producing the antibodies BDA8 and B9 have been deposited with the A.T.C.C. under the Budapest Treaty and the deposit information including the cell line producing the antibodies, the A.T.C.C. accession numbers for the cell lines and the dates that the cell lines were deposited (both prior to the effective filing dates of the instant application) are disclosed in the instant application at pages 33, lines 18-21 (BDA8) and page 36, lines 14-17 (B9). Applicants have included in new claims 64, 69, 81 and 93 (which correspond to canceled claims 9, 13, 26 and 34, respectively) the corresponding A.T.C.C. designation numbers. Moreover, Applicants' undersigned attorney, on behalf of Applicants and their assign, hereby declare that upon indication of an allowable claim to the use of BDA8 and/or B9 antibody or the cell line that produces BDA8 and/or B9 that, as required under 37 C.F.R. § 1.808(a)(2) all restrictions imposed by the depositor on the availability to the public of the deposited materials will be irrevocably removed upon the granting of the patent. In view of the above remarks, reconsideration and withdrawal of the objection to the specification and rejection of the claims under 35 U.S.C. section 112, first paragraph are respectfully requested.

Rejection Under 35 U.S.C. § 112 Second Paragraph

Claims 9, 13, 26 and 34 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Applicants respectfully traverse these rejections to the extent they are applied to the new claims.

Claims 9, 13, 26 and 34 have been objected under 35 U.S.C. § 112, second paragraph as indefinite for using the abbreviations "BDA8 and B9". Claims 9, 13, 26 and 34 have been replaced with new claims 64, 69, 81 and 93. As suggested by the Examiner Applicants have incorporated the ATCC Accession numbers for the cell lines that produce BDA8 and B9 into new claims 64, 69, 81 and 93. Applicants therefore respectfully request that the 35 U.S.C. § 112, second paragraph rejection be withdrawn.

Allowable Subject Matter

As suggested by the Examiner claims 2, 5-8, 10-12, 14, 20, 23-25, 27 and 30-33 have been rewritten in independent form.

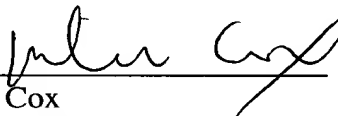
Conclusion

In view of the above argument, and the amendments to the claims, allowance of each of the pending claims as amended herein is earnestly solicited. If the Examiner believes that a telephone conference would expedite the prosecution of this application, please call the undersigned at (617)-679-2079.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 02-2327**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Date: 7/31/01

  
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